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Advances in electronic fetal monitors — real or imaginary

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1 Introduction

Electronic fetal monitoring is now an accepted part of the management of labor and pregnancy [8]. However, the interpretation of the data produced by the electronic fetal monitor (EFM) still presents problems to the user. While differing levels of staff expertise may contribute to these difficulties the differences in signal processing and display between various models of EFM further complicates the interpretation of the trace. The latest generation of EFM all use microprocessors to perform the signal processing and a few use solid-state printers to produce the fetal heart rate (FHR) and uterine activity trace. In some instruments this has led to a real advance in the quality of the FHR data produced (particularly the ultrasound detection of fetal heart movements) while in others any improvement in the FHR trace is purely illusory.

2 Factors affecting the FHR trace

The FHR variability is the fluctuation in the baseline heart rate over a period of 15 to 20 minutes. The component part of the variability is the beat to beat variation. The cumulative effect of small changes in FHR from one beat to the next is to form oscillations in the baseline FHR. These oscillations have an amplitude of 5 to 15 beat per minute (bpm) and it is the presence or absence of these which is one of the indicators used by the clinician to interpret the FHR trace [9]. The clinical importance of the beat to beat changes in the human fetus is at present unclear. The value of the mean absolute beat to beat variation is between 2 to 3 ms [4] and 12–20% of the interval differences are less than 1 ms [10]. Accurate measurement of human FHR variation therefore requires a precision of at least ± 1 ms [4, 10, 11]. However, the scale and speed sensitivities of EFM (20 or 30 bpm/cm and 1, 2 or 3 cm/min respectively) do not allow these small individual beat to beat changes to be resolved.

Curriculum vitae

MICHAEL CARTER *is the Manager of the Bio-Medical Technology Group and Project Leader for the Departments of Health's Programme for the Evaluation of Cardiotocographs. He received his Higher National Diploma in Electrical Engineering in 1972. He is named inventor on a patent for the control of oxytocin infusion and was awarded the 1979 AAMI Manuscript Award for the best paper presented at the meeting on new applications for improved patient care through technology.*

A number of factors will affect the accuracy and resolution of the FHR trace produced by the EFM. The major factors are:

1) Signal detection and rejection of noise
2) processing the detected signal
3) display of the derived FHR data.

2.1 Signal detection and rejection of noise

The signal used to derive the FHR is usually obtained by either an electrode attached to the fetal presenting part (FECG) or the detection of fetal heart movements with doppler ultrasound. In modern EFM the determination of FHR is different for each of these modes.

FHR determination from the FECG: The R-wave of the FECG presents an easily recognizable trigger point for the measurement of pulse interval. The FECG signal is often contaminated by noise and this can have a large effect on the accuracy of FHR determination. The frequency distribution of the ratio of the peak to peak amplitudes of the signal to noise is approximately lognormal with a geometric mean of 17%. The upper and lower limits of the range are 8% and 39% respectively [2]. The standard deviation of triggering errors caused by noise are shown in figure 1 for a number of EFM. It can be seen that as the noise increases the error also increases. The number of missing data is also related to the noise levels and at the upper limit may result in over 50% of the FECG being undetected. When there is no noise present all the EFM detected the R-wave with an precision of less than 0.5 ms. However, as the noise level increases, there were large differences between EFM. In some instruments the errors caused by the noise alone may be of the same order of magnitude as the true physiological variation of FHR and a FHR trace with reduced variability could be misinterpreted as being normal.

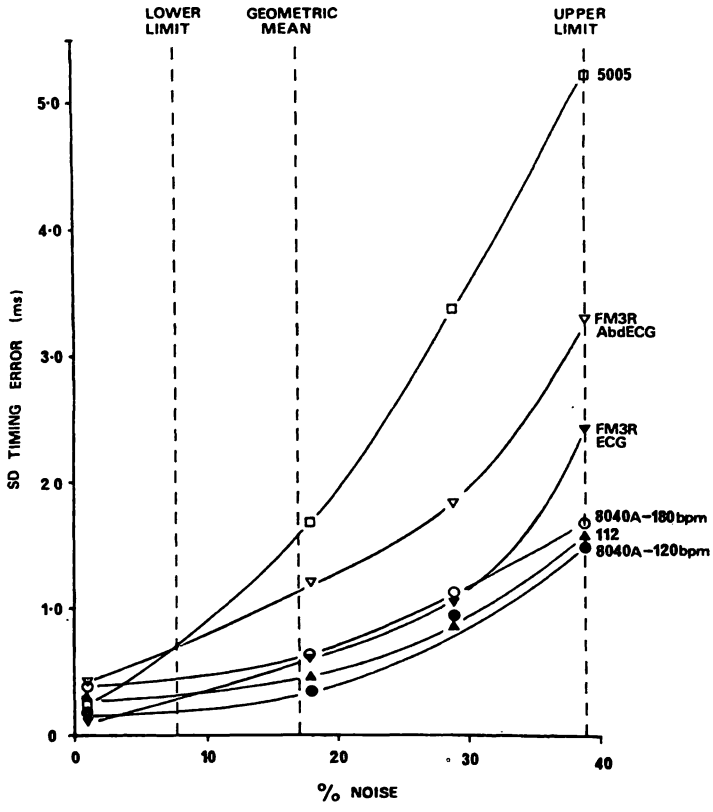

Figure 1. The effect of noise on the accurate determination of the trigger point for the measurement of pulse interval. The standard deviation (SD) of timing errors for four EFM are shown as a function of the ratio (%) of the peak to peak amplitudes of the signal to noise.

FHR determination from doppler ultrasound: The slow risetime and flat peak of the ultrasound signal, in early EFM, gave rise to large errors in the FHR. The appearance of the FHR trace in these instruments was improved by averaging the FHR. However, with the introduction of microprocessors into EFM it has become possible to use complex signal processing techniques to derive the FHR from the doppler signal. All modern EFM use autocorrelation techniques to derive the heart interval. The technique has the advantage that a more accurate estimation of the FHR and a reduction in the amount of missing data can be made from the autocorrelation function than from the actual doppler waveform. However, there are a number of shortcoming of which the user should be aware.

a) There is an underestimation of the beat to beat variation and consequently reduced variability [7].
b) It is much easier inadvertently to monitor the heart rate of the woman instead of the fetus [1, 5].
c) Half or double the actual FHR may be output [1].

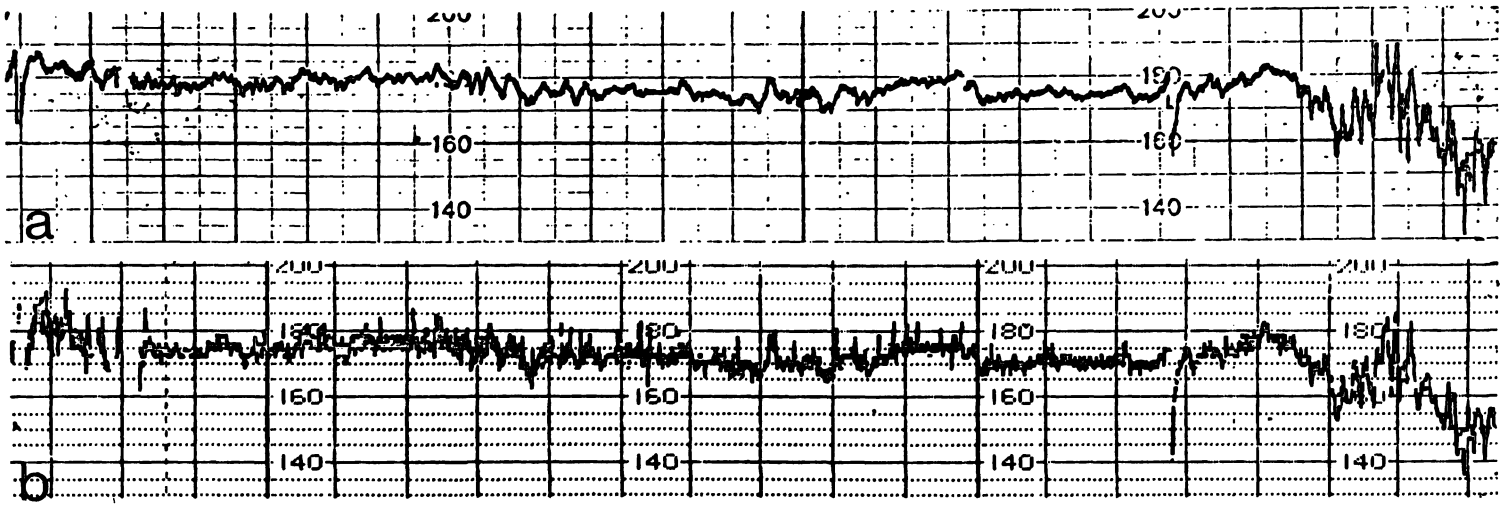

Figure 2. Simultaneous recordings of a FECG made on two different EFM. a) FHR resolution of ± 0.66 bpm; b) FHR resolution of ± 4.0 bpm.

These artefacts may be obvious when there is a large step change in FHR but in cases where the maternal and fetal heart rates are similar, for example, during salbutamol infusion, the user may be misled by the trace produced.

2.2 Processing and display of the derived FHR data

The resolution with which the EFM is able to display the changes in FHR on the chart recorder will affect the clinicians ability to interpret the data. The resolution of the FHR trace is dependent on two main factors; the chart recorder resolution and the signal processing.

To enable the data to be processed by the microprocessor the input signal must be digitized. A resolution of ± 1% of the FHR is required for adequate interpretation of the trace [6]. Nine bit digitization is therefore required if the 1% resolution is to be maintained. Most EFM digitize the data to eight bit accuracy which results in a FHR resolution of ± 0.82 bpm (30–240 bpm scale sensitivity). Further degradation occurs in the majority of instruments because the FHR is calculated to the nearest integer, resulting in an accuracy of ± 1 bpm. In some EFM the resolution of the FHR trace decreases as the FHR increases. For example, in one instrument there is a resolution of ± 1 bpm at 60 bpm but this decreases to ± 4bpm at 200 bpm. The resultant FHR trace will therefore show artefactually high variability as the FHR increases (figure 2).

Further degradation of the FHR trace results from the use of linear solid-state printers. The first instruments to incorporate these printers had a FHR resolution of ± 1.5 bpm due to its low print-head density. While improvements

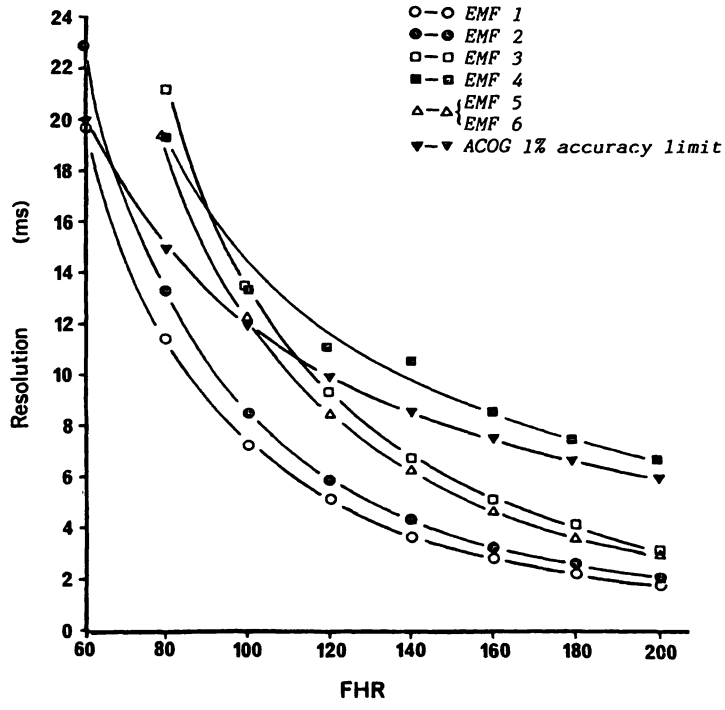

Figure 3. FHR resolution (in ms) measured from the traces of six EFM.

have been made in solid-state printer technology the full potential has not been exploited and in EFM incorporating these printers the resolution is reduced when compared to the EFM with an analogue recorder.

The cumulative effect of these factors on the FHR resolution has been measured and the results for 6 different EFM are shown in figure 3. Only 2 EFM were within the ± 1% resolution limits for the whole of their dynamic range. The effect of reduced resolution on FHR recordings obtained from commercially available EFM are shown in figure 4.

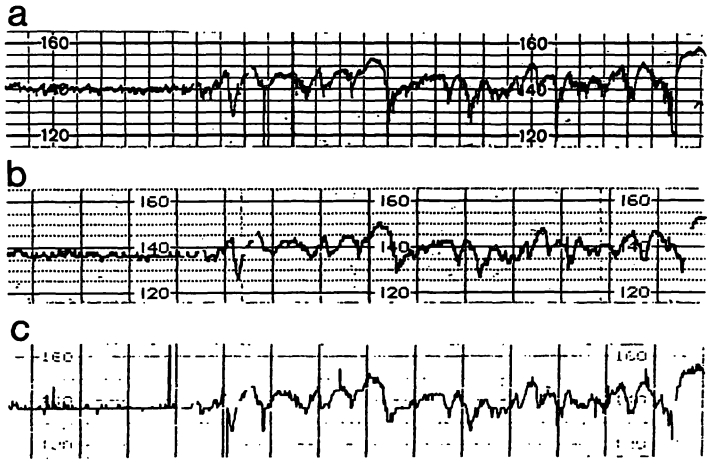

Figure 4. Simultaneous recordings showing the effect of reduced resolution on the FHR trace produced by three commercially available EFM: a) resolution of ± 0.66 bpm (EFM 1, Figure 3); b) resolution of ± 1.6 bpm (EFM 4, Figure 3); c) resolution of ± 2.5 bpm.

3 Conclusions

Noise on the FECG signal in some EFM can produce artefactual FHR variability of the same magnitude as the true physiological variability. Noise can be minimized by correct electrode placement and reassurance of the woman to reduce maternal movements. The use of microprocessors in EFM has in some cases produced a real improvement in the FHR trace and reduced the amount of missing data. While in other EFM the quality of the FHR trace has declined because of the use of unsuitable printers, imprecise signal processing and lack of resolution. This is most evident in the range of cheap antenatal EFM aimed at the General Practitioner market.

Manufacturers tend to keep their signal processing techniques confidential for commercial reasons which makes it difficult for the user to validate the results produced by an EFM. Many of the cheaper EFM have no output signals other than the FHR trace thereby making it impossible to validate their processing other than by eye.

To aid the user to determine the best EFM for their particular application the UK Departments of Health (DHSS) has an evaluation programme for EFM [3]. Comparative reports are published in Health Equipment Information [6] and can be obtained from the DHSS.

Summary

Changes in the technologies used in the latest generation of electronic fetal monitors has resulted generally in an improvement in the quality of the FHR data produced. However, in a number of instruments the use of inappropriate printers and signal processing has led to a degradation in the FHR trace. This may result in difficulties in interpretation of the data thereby putting the compromised fetus at risk. This paper discusses

1. the factors which affect the interpretation of the data, such as signal detection and rejection of noise,
2. errors due to the signal processing and rate determination, and
3. the effect of the chart recorder on the presentation of the data.

Finally information is given about the UK Departments of Health evaluation programme for electronic fetal monitors (cardiotocographs).

Keywords: Electrocardiography, equipment safety, evaluation studies, fetal monitoring, heart rate, signal processing, ultrasound instrumentation.

Zusammenfassung

Sind Fortschritte beim elektronischen fetalen Monitoring realistisch oder nur Wunschvorstellung?
Die neue Generation elektronischer Monitoren zur Überwachung des Feten weist technologische Fortschritte auf, die insgesamt die Qualität der aufgezeichneten Herzfrequenzkurven verbessert haben. Bei einigen Geräten ist jedoch die Aufzeichnung und Signalverarbeitung unzureichend, so daß das FHR-Signal degradiert ist. Das führt zu Schwierigkeiten bei der Dateninterpretation und möglicherweise unnötigen Gefährdung des Risikofeten. In dieser Arbeit werden diskutiert:

1. Faktoren, die die Dateninterpretation beeinflussen, wie z. B. Signalaufnahme und -filterung,
2. Fehler, die auf die Signalverarbeitung und Frequenzbestimmung zurückgehen,
3. Beeinflussung der Datendarstellung durch den Registrierapparat.

Schließlich wird über das Programm zur Bewertung elektronischer fetaler Monitoren (Kardiotokographen) der ‚UK Departments of Health' berichtet.

Schlüsselwörter: Auswertung, Elektrokardiographie, fetale Überwachung, Herzfrequenz, Sicherheit technischer Geräte, Signalverarbeitung, Ultraschallausrüstung.

Résumé

Progrès du monitorage électronique du fœtus: réalité ou fiction
Les changements des technologies utilisées pour la dernière génération d'appareils de surveillance électronique du fœtus ont entrainé, en règle générale, une amélioration de la qualité de la représentation des données du RCF. Toutefois, pour bon nombre d'appareils, l'emploi d'imprimantes et de traitements de signal non adaptés a conduit à une dégradation du tracé du RCF. Cela peut entrainer des difficultés dans l'interprétation des données et de ce fait induire un risque pour les fœtus concernés. Cet article discute:

1. Les facteurs qui influencent l'interprétation des données, tels que la détection du signal et l'élimination du bruit de fond;
2. Les erreurs secondaires au traitement du signal et à la détermination du rythme;
3. L'effet de l'appareil d'enregistrement sur la présentation des données.

Enfin, sont données des informations concernant le programme d'évaluation des appareils de surveillance électronique du fœtus (cardiotocographes) des départements de santé de Grande-Bretagne.

Mots-clés: Appareillage ultrasonore, électrocardiographie, études d'évaluation, fréquence cardiaque, sécurité des équipments, surveillance fœtale, traitement du signal.

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